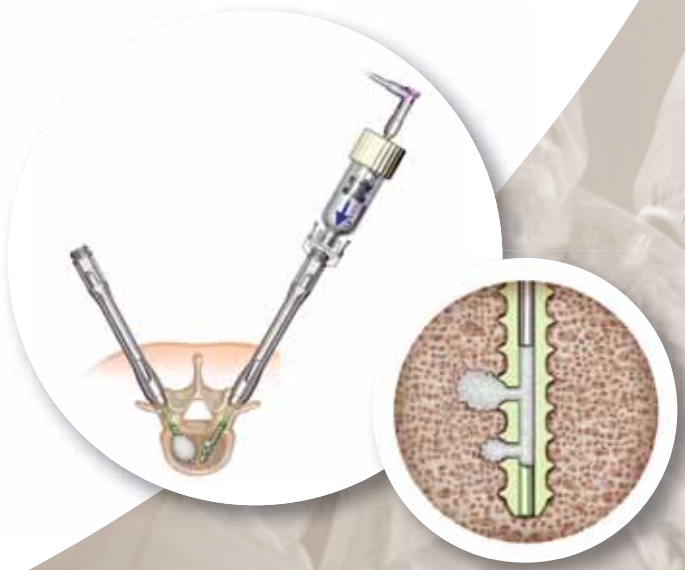
VIPER®

Cortical Fix Fenestrated Screw

Surgical Technique & Product Catalogue

Guide for Open & MIS Procedures



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INTRODUCTION

The VIPER® Cortical Fix Fenestrated Screw System is the first pedicle screw implant to offer enhanced fixation in both the pedicle and vertebral body. The Cortical Fix thread form doubles the number of screw/bone contact points thereby increasing the resistance to pull out in the pedicle. With the additional option to inject cement through the screw shank and into the vertebral body, this implant is key for patients with diminished bone quality in which screw purchase is a concern.

This Surgical Technique describes Open and MIS procedures and instruments that are specific to the VIPER Cortical Fix Fenestrated Screw System with the CONFIDENCE SPINAL CEMENT SYSTEM® or the V-Max® Mixing and Delivery System and the VERTEBROPLASTIC® Radiopaque Resinous Material. When using the Cortical Fix Fenestrated Screw System, it is important to refer to the appropriate EXPEDIUM® Spine System or VIPER® MIS Spine System Surgical Technique Guides for comprehensive surgical procedure and system information.

For cement augmentation refer to the package inserts and the surgical technique manual for CONFIDENCE SPINAL CEMENT SYSTEM or the V-Max Mixing and Delivery System and the VERTEBROPLASTIC Radiopaque Resinous Material.

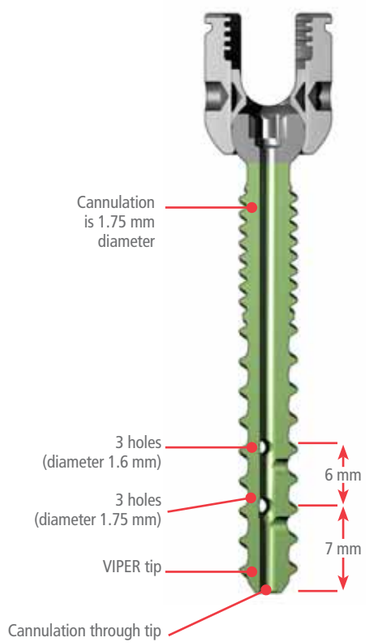
CONTENTS

Screw Design

- The VIPER Cortical Fix Fenestrated Screw is a fully cannulated polyaxial screw with 6 fenestrations at the distal end of the screw.
- The cannulation and fenestrations allow for the injection of bone cement through the screw.

- Earlier thread start compared to standard EXPEDIUM and VIPER screws.
- Cortical thread form designed to engage the pedicle wall.

- Available in screw diameters: 5, 6, 7, 8, 9 and 10 mm
- Available in screw lengths: 30-80 mm (in 5 mm increments)
- 6 fenestrations for screw lengths 35 mm and longer
- 3 fenestrations for 30 mm screw length



The VIPER Cortical Fix Fenestrated Screw delivery instruments, available for both Open and MIS techniques, consist of alignment devices and cement delivery cannulas which rigidly attach to the alignment devices.

These instruments allow cement injection directly through the screw shank while staying clear of the fluoroscopy field.

Components for Open Procedures

Open Alignment Sleeve | Open Alignment Device | Open Cement Cannula | Plunger | Stylet | Mini Stylet

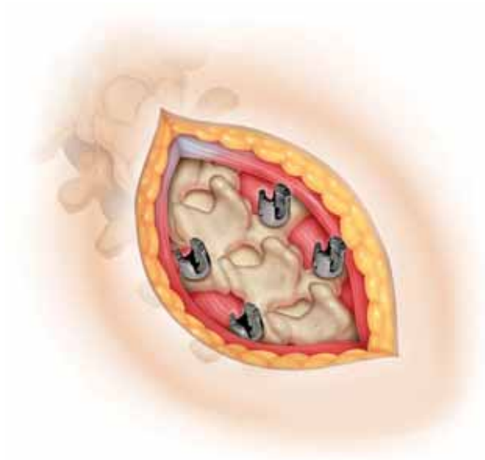
Components for MIS Procedures

Cortical Fix Fenestrated Screw with VIPER Extension | MIS Alignment Device | MIS Cement Cannula | Plunger | Stylet | Mini Stylet

STEP 1: PREPARE THE SPINE

- Refer to the EXPEDIUM or VIPER Surgical Techniques for pedicle targeting and preparation.
- Pedicle preparation is performed using a selection of awls, pedicle probes, drill bits, ball tip feelers and bone taps.

NOTE: If a biopsy is completed prior to screw placement, care should be taken not to place the tip of the biopsy needle beyond the desired location of the screw tip in order to reduce the risk for cement leakage or extravasations.



STEP 2: INSERTION OF SCREWS

- The Screws are inserted for Open or MIS procedures using the same technique as the EXPEDIUM or VIPER polyaxial screws respectively.

  Please refer to the EXPEDIUM or VIPER System Surgical Techniques.
- For MIS screw insertion, do not remove the VIPER screw extension after screw insertion. The extension must remain in place throughout cement delivery.

NOTE: Fenestrated screws should NOT be placed bicortically. It is very important not to breach the pedicle wall or anterior cortex of the vertebral body to avoid cement extrusion into retroperitoneal space. Use appropriate imaging techniques, such as fluoroscopy, to confirm screw placement.

Step 3: Open Procedure *(Proceed to Page 6 for MIS Procedure)*

STEP 3a: ASSEMBLY OF THE OPEN ALIGNMENT GUIDE

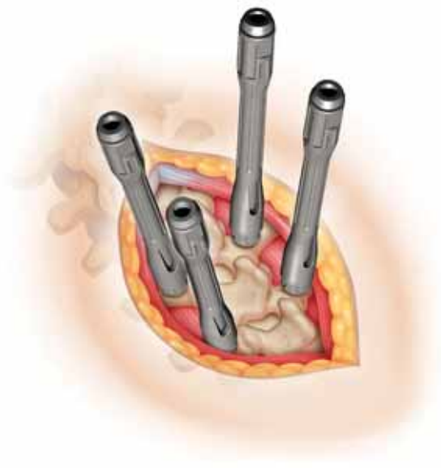
- Check that the alignment device and alignment sleeve are clear of any cement from prior use.
- Insert the alignment device into the alignment sleeve and push the two pieces together until you hear a click.

- Repeat this step for each screw intended for cement augmentation. Proceed to Page 7 for remainder of the technique.

NOTE: The alignment device MUST be used for each screw intended for cement augmentation. Without the alignment device, there is a potential risk of cannula breakage. Use of the alignment device will prevent undue stress from being applied to the cannula.

STEP 3b: ALIGNMENT OF THE SCREW

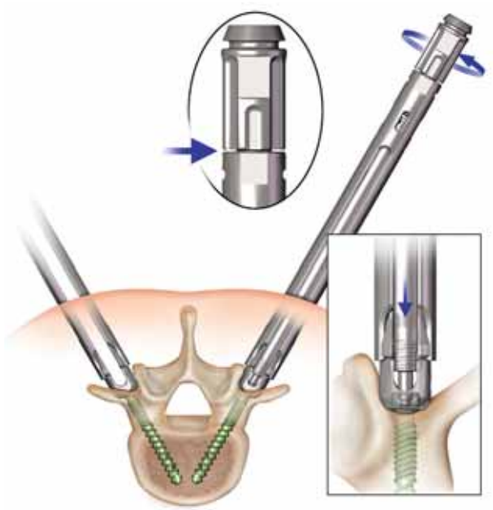
- Align the tabs of the alignment sleeve with the rod slot in the screw head, ensuring that the soft tissue does not impinge on the connection of the alignment sleeve to the screw head.
- Thread the assembled alignment guide into the screw head. This will align the screw shank to the screw head.
- Confirm that the alignment device is fully seated by checking that the alignment guide and alignment sleeve are in close proximity (See detail).



Step 3: MIS Procedure

STEP 3: ALIGNMENT OF SCREW

- Check that the alignment device is clear of any cement from prior use.
- Insert the MIS alignment device into the VIPER extension and thread it into the screw head. This will align the screw shank to the screw head.
- Confirm that the alignment device is fully seated by checking that the alignment device handle and VIPER Screw extension are in close proximity (See detail).



- Repeat this step for each screw intended for cement augmentation.

NOTE: The alignment device MUST be used for each screw intended for cement augmentation. Without the alignment device, there is a potential risk of cannula breakage. Use of the alignment device will prevent undue stress from being applied to the cannula.

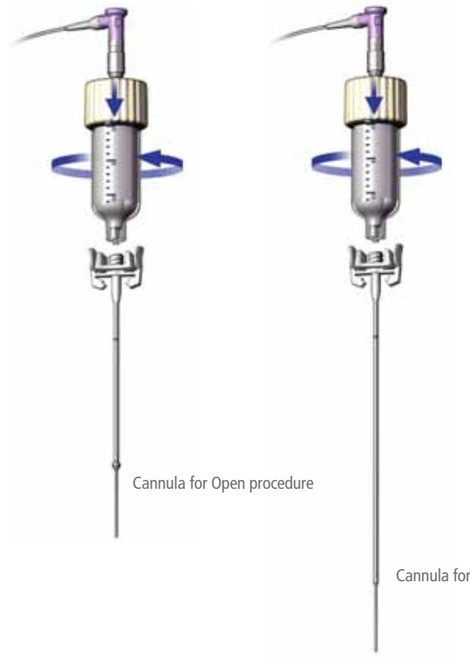
NOTE: The remainder of the procedure is identical for Open and MIS Procedures.

STEP 4a: CEMENT PREPARATION

- Once the Fenestrated Screws are in place and the alignment devices are attached, prepare the cement according to the manufacturer's published instructions.

NOTE: Bone cement should be prepared as per the cement package insert or surgical technique manual. Time/Temperature Graph provided in the package insert or surgical technique manual should be followed carefully.

- When augmenting multiple screws/levels with cement, attention must be paid not to exceed the working time of the cement prior to the completion of cement delivery through the screw. When the cement working time is close to completion, a new cement, cement delivery system package and cannula should be used for any remaining levels/screws.



Cannula for Open procedure

Cannula for MIS procedure

STEP 4b: CONNECTION OF CANNULA TO THE CEMENT RESERVOIR

- Thread the CONFIDENCE SPINAL CEMENT SYSTEM reservoir onto the appropriate cannula (Open or MIS).

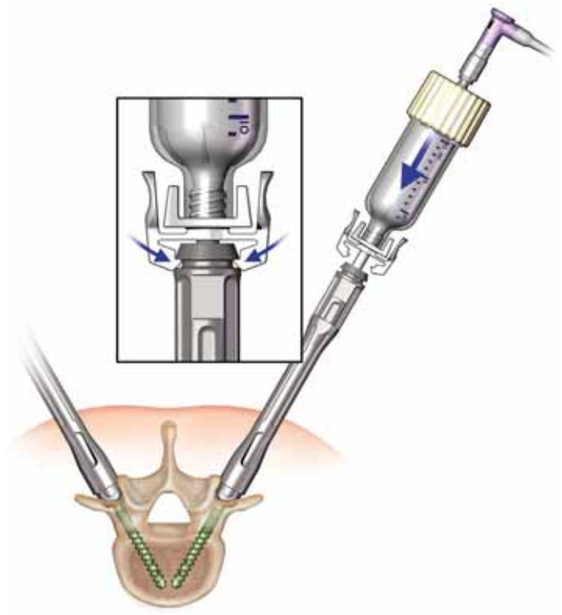
NOTE: If using the V-Max Mixing and Delivery System and the Vertebroplastic Radiopaque Resinous Material, the CONFIDENCE System Luer Adapter (2839-99-001) is screwed onto the cannula before attaching those systems to the cannula.

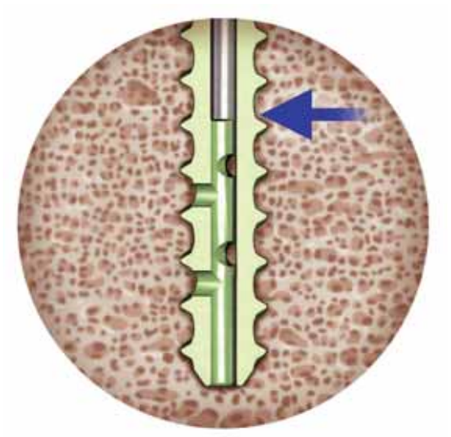
NOTE: From this point forward, images portray instruments specific to the Open procedure. The MIS technique is identical.

STEP 4c: ATTACHMENT OF CEMENT CANNULA TO ALIGNMENT GUIDE

- Place the cannula with cement reservoir through the alignment guide and into the screw shank.
- The cannula will click onto the alignment guide.

NOTE: To ensure that the cannula is correctly positioned to deliver cement, the cannula MUST click into place before proceeding to the next step.





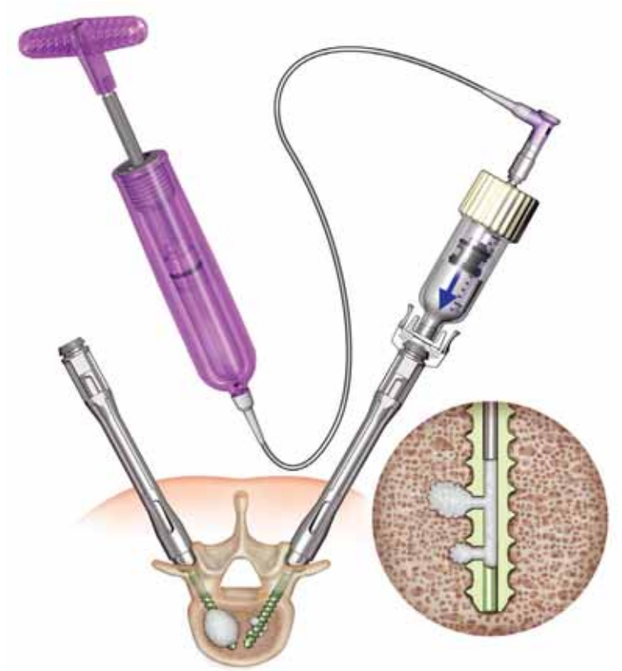
- When the cannula is properly positioned in the screw shank, the tip will be just above the first fenestration.

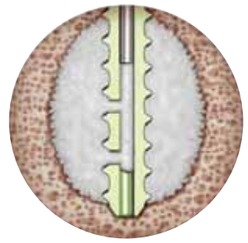
NOTE: If there is trouble inserting the cannula into the screw shank, ensure that the alignment device is properly threaded into the screw head.

STEP 5: CEMENT DELIVERY

- Follow the instructions from the respective bone cement and delivery system package inserts to introduce the cement through the delivery cannula.
- Use fluoroscopy throughout the procedure to verify and monitor cement flow as appropriate.

NOTE: Controlled delivery is essential to proper screw augmentation. Overly aggressive cement injection may result in cement leakage and unsatisfactory results. Immediately stop cement injection if extravasation is detected.

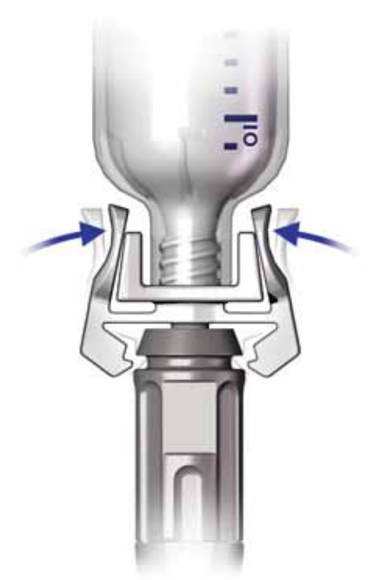


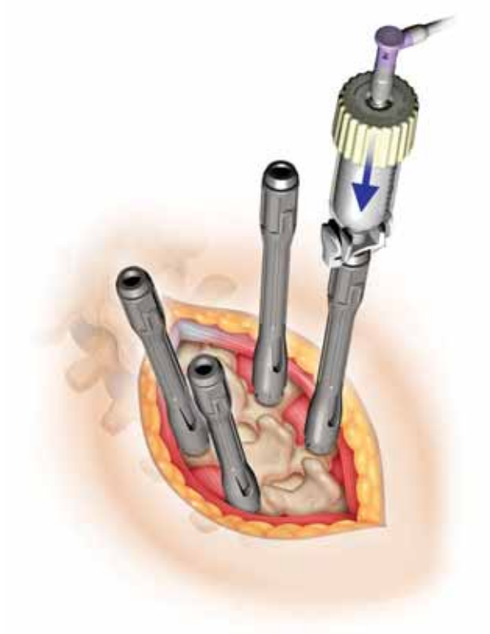


STEP 6: REMOVAL OF DELIVERY CANNULA

- When the appropriate amount of cement has been introduced, stop cement introduction as indicated per the respective bone cement technique.
- Disengage the cannula from the alignment guide by depressing the tabs on each side of the cannula and remove it from the screw as soon as cement injection is completed and flow has stopped through the cannula.

NOTE: It is essential to confirm that cement flow has stopped before disengaging the cement delivery system from the screw head.





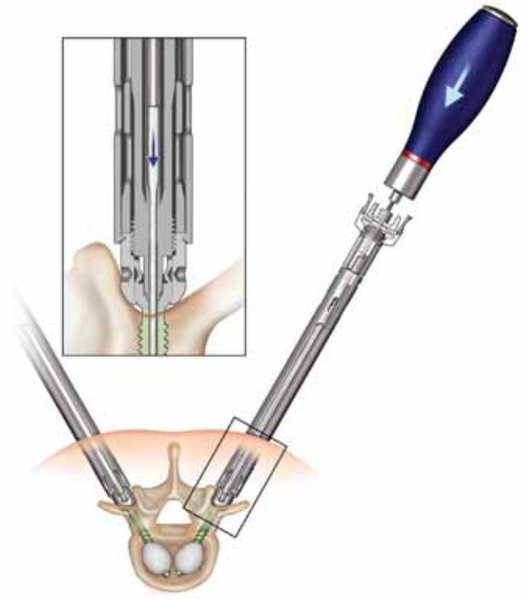
STEP 7a: SUBSEQUENT LEVEL AUGMENTATION

- Place the existing cannula and cement reservoir into the next alignment guide as per step 4c and follow the instructions through step 6.
- Repeat for each desired vertebral level, ensuring that cement flow has stopped between each level.
- If an additional cement package is needed, remove the existing cannula and attach a new cannula.
- If additional cement is needed beyond its working time, dispose of the cement and cannula. Use a new cannula and mix a new dose of cement for remaining screws.

STEP 7b: SUBSEQUENT LEVEL AUGMENTATION

Optional Step

- The plunger can be used to pass the cement remaining in the cannula into the screw after the cement reservoir has been emptied. Detach the reservoir from the cannula and proceed with plunger insertion.



STEP 8: REMOVAL OF ALIGNMENT DEVICES

- After cement introduction, the alignment devices can be unthreaded from the screw head.
- Apply counter-torque using the VIPER wrenches on VIPER screw extension while removing alignment devices.

NOTE: The VIPER wrenches can be used for counter torque on the Open Alignment Guides as well.

STEP 9: ROD INSERTION AND LOCKING

- Choose the appropriate length rod with the desired contour. Place the rod into the polyaxial screw heads.
- Capture the rod into the implant by inserting the single innie setscrew.
- The alignment guide can be used to help position the head and reduce the chance of cross-threading.

NOTE: After cement injection, no torsional movement should be applied to the screw throughout the cement setting time outlined in the respective package insert. At the end of the case, any opened cannulas must be discarded.

- Once the cement is set as outlined in the respective package insert, final tighten with the Hexlobe Shaft inserted into the T-Handle Torque Wrench, set to 80 in-lb.
- Insert the shaft through the Counter Torque Device and into the Single Innie. Rotate the T-Handle clockwise until it clicks and resistance is no longer evident.

STEP 10: RESIDUAL CEMENT REMOVAL

- After use, the Alignment Devices should be visually inspected for any cement.
- If cement remains in the alignment device, insert the Stylet through Alignment Device and rotate to ensure any cement is removed.
- Insert the Mini-Stylet into the threaded tip of the Alignment Device.
- If cement remains in the device, repeat cleaning steps above or return it to DePuy Spine.

VIPER Cortical Fix Fenestrated Screws (Polyaxial, Titanium Screws for a 5.5mm Rod)

5mm	
1867-27-530	5mm x 30mm
1867-27-535	5mm x 35mm
1867-27-540	5mm x 40mm
1867-27-545	5mm x 45mm
1867-27-550	5mm x 50mm
1867-27-555	5mm x 55mm
1867-27-560	5mm x 60mm
1867-27-565	5mm x 65mm
1867-27-570	5mm x 70mm
1867-27-575	5mm x 75mm
1867-27-580	5mm x 80mm

6mm	
1867-27-630	6mm x 30mm
1867-27-635	6mm x 35mm
1867-27-640	6mm x 40mm
1867-27-645	6mm x 45mm
1867-27-650	6mm x 50mm
1867-27-655	6mm x 55mm
1867-27-660	6mm x 60mm
1867-27-665	6mm x 65mm
1867-27-670	6mm x 70mm
1867-27-675	6mm x 75mm
1867-27-680	6mm x 80mm

VIPER Cortical Fix Fenestrated Polyaxial Screws

7mm	
1867-27-730	7mm x 30mm
1867-27-735	7mm x 35mm
1867-27-740	7mm x 40mm
1867-27-745	7mm x 45mm
1867-27-750	7mm x 50mm
1867-27-755	7mm x 55mm
1867-27-760	7mm x 60mm
1867-27-765	7mm x 65mm
1867-27-770	7mm x 70mm
1867-27-775	7mm x 75mm
1867-27-780	7mm x 80mm

8mm	
1867-27-830	8mm x 30mm
1867-27-835	8mm x 35mm
1867-27-840	8mm x 40mm
1867-27-845	8mm x 45mm
1867-27-850	8mm x 50mm
1867-27-855	8mm x 55mm
1867-27-860	8mm x 60mm
1867-27-865	8mm x 65mm
1867-27-870	8mm x 70mm
1867-27-875	8mm x 75mm
1867-27-880	8mm x 80mm

VIPER Cortical Fix Fenestrated Polyaxial Screws

9mm	
1867-27-930	9mm x 30mm
1867-27-935	9mm x 35mm
1867-27-940	9mm x 40mm
1867-27-945	9mm x 45mm
1867-27-950	9mm x 50mm
1867-27-955	9mm x 55mm
1867-27-960	9mm x 60mm
1867-27-965	9mm x 65mm
1867-27-970	9mm x 70mm
1867-27-975	9mm x 75mm
1867-27-980	9mm x 80mm

10mm	
1867-27-030	10mm x 30mm
1867-27-035	10mm x 35mm
1867-27-040	10mm x 40mm
1867-27-045	10mm x 45mm
1867-27-050	10mm x 50mm
1867-27-055	10mm x 55mm
1867-27-060	10mm x 60mm
1867-27-065	10mm x 65mm
1867-27-070	10mm x 70mm
1867-27-075	10mm x 75mm
1867-27-080	10mm x 80mm

Instruments Specific to Open Procedures

Part Number	Part Description
2797-26-401	Open Alignment Device
2797-26-509	Open Alignment Sleeve
2797-26-500	Open Cannula (pre-packed sterile/single use)

Instruments Specific to MIS Procedures

Part Number	Part Description
2797-26-400	MIS Alignment Device
2797-26-524	Loading Block
2797-26-508	MIS Cannula (pre-packed sterile/single use)

Instruments Common to Open and MIS Procedures

Part Number	Part Description
2797-26-403	Stylet
2797-26-511	Mini Stylet
2797-26-402	Plunger
2867-45-155	VIPER Wrench

Trays and Caddies

Part Number	Part Description
2797-26-520	Open Instrument Tray
2797-26-522	MIS Instrument Tray
2797-26-523	Instrument Tray Lid
2797-26-525	Implant Tray
2797-26-526	Implant Tray Lid
2797-26-515	5.0mm Caddy
2797-26-516	6.0mm Caddy
2797-26-517	7.0mm Caddy
2797-26-518	8.0mm Caddy
2797-26-529	9.0 & 10.0mm Cassette
2797-26-521	9.0 & 10.0mm Implant Tray & Lid

INDICATIONS FOR USE
The VIPER® Fenestrated Screw System is intended to be used with the CONFIDENCE SPINAL CEMENT SYSTEM® or the V-MAX® Mixing and Delivery System and the VERTEBROPLASTIC® Radiopaque Resinous Material to provide immobilization and stabilization of spinal segments in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine in patients with diminished bone quality (e.g., osteoporosis, osteopenia, metastatic disease). It is intended to provide temporary internal support and fixation while fusion mass is consolidating or fracture is healing, or for the palliative reconstruction of the tumor patients.

WARNINGS, PRECAUTIONS & CONTRAINDICATIONS
Refer to the VIPER FENESTRATED SCREW SYSTEM IFU for complete information.

Limited Warranty and Disclaimer: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

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*For recognized manufacturer, refer to product label.

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